



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/257,272 02/25/99 HU

J PF112P2D2

HM12/0418

MICHAEL M WALES  
HUMAN GENOME SCIENCES INC  
9410 KEY WEST AVENUE  
ROCKVILLE MD 20850

EXAMINER

SADUD, C

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

04/18/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/257,272

Applicant(s)  
HU et al.

Examiner  
Christine Saoud

Group Art Unit  
1646



☐ Responsive to communication(s) filed on \_\_\_\_\_.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-32 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-32 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1646

## **DETAILED ACTION**

### ***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-16, 20, drawn to nucleic acids, vectors, host cells and recombinant methods of protein production, classified in at least class 435, subclass 69.4, for example.
  - II. Claims 17-19, 21 drawn to polypeptides, classified in class 530, subclass 399, for example.
  - III. Claim 22, drawn to an antibody, classified in class 530, subclass 387.1, for example.
  - IV. Claim 23, drawn to an agonist compound of undefined constitution, classified in class undetermined, subclass undetermined.
  - V. Claim 24, drawn to an antagonist compound of undefined constitution, classified in class undetermined, subclass undetermined.
  - VI. Claim 26, drawn to a method of treatment by administration of the polypeptide, classified in class 514, subclass 2, for example.
  - VII. Claim 27, drawn to methods of treatment by administration of the polynucleotide, class 514, subclass 44, for example.
  - VIII. Claim 28, drawn to methods of treatment by administration of a compound of unspecified constitution (specified as an agonist), class undeterminable, subclass undeterminable.
  - IX. Claim 29, drawn to methods of treatment by administration of a compound of unspecified constitution (specified as an antagonist), class undeterminable, subclass undeterminable.
  - X. Claim 30, drawn to a diagnostic method which includes detecting DNA, classified in class 536, subclass 24.3, for example.

Art Unit: 1646

XI. Claim 31, drawn to a diagnostic method which includes detecting the polypeptide, classified in class 436, subclass 501, for example.

XII. Claim 32, drawn to a method of identifying a binding partner, classified in class 436, subclass 501, for example.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Group I could be used in an entirely different method, such as in a method of detection of the polynucleotide in a sample, rather than in a method of making the polypeptide.

4. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II could be used for an entirely different purpose such as in stimulating cell growth, rather than for the production of antibodies of Group III.

5. Inventions I-V are also are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they

Art Unit: 1646

have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to chemically different compounds which can be made and used without each other. Furthermore, the inventions of Groups I-V lack a common utility which is based upon a common special technical feature which is disclosed as being responsible for the common utility.

6. Inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Group II could be used in an entirely different manner, such as in a method of making antibodies rather than in the method of Group VI.

7. Inventions (I and III-V) and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the DNA, antibody, activation compound, and inhibiting compound of Groups I and III-V are not required for the method of Group VI.

8. Inventions I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

Art Unit: 1646

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Group I could be used in an entirely different manner, such as in a method of recombinant production of the polypeptide rather than in the method of Group VII.

9. Inventions I and VIII-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the DNA of Group I is not required for the methods of Groups VIII-XI.

10. Inventions (I-V) and XII are unrelated, respectively. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that none of the compounds of Groups I-V are required for the method of Group XII.

11. Inventions II and VII-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the polypeptide of Group II is not required for the methods of Groups VII-XI.

Art Unit: 1646

12. Inventions III and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Group III could be used in an entirely different manner, such as in a method of protein purification rather than in the method of Group XI.

13. Inventions III and VII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the antibody of Group III is not required for the methods of Groups VII-X.

14. Inventions IV and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compound of Group IV could be used in an entirely different manner, such as in a method of antibody production rather than in the method of Group VIII.

15. Inventions IV and (VII, IX-XI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP

Art Unit: 1646

§ 808.01). In the instant case the different inventions are not required one for the other in that the compound of Group IV is not required for the methods of Groups VII and IX-XI.

16. Inventions V and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compounds of Group V could be used in an entirely different manner, such as in a method of antibody production rather than in the method of Group IX.

17. Inventions V and (VII-VIII, X-XI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the compound of Group IV is not required for the methods of Groups VII-VIII and X-XI.

18. Inventions VI-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to methods which have different method steps, starting materials and goals.



Art Unit: 1646

19. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the necessity for non-coextensive literature searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

20. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Saoud, Ph.D., whose telephone number is (703) 305-7519. The examiner can normally be reached on Monday to Friday from 8AM to 3PM.

Art Unit: 1646

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

April 18, 2000

**CHRISTINE SAOUD  
PATENT EXAMINER**

*Christine Saoud*



# RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

FIRM:

PAGES, INCLUDING COVERSHEET:

PHONE NUMBER:

TO EXAMINER:

ART UNIT:

SERIAL NUMBER:

FAX/TELECOPIER NUMBER: (703) 305-3704

**PLEASE NOTE: THIS FACSIMILE NUMBER IS TO BE USED ONLY  
FOR RESPONSES TO RESTRICTIONS.**

COMMENTS: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

IF YOU HAVE NOT RECEIVED ALL THE PAGES OF THIS TRANSMISSION, PLEASE CONTACT THE ATTORNEY AT THE TELEPHONE NUMBER LISTED ABOVE.

IN COMPLIANCE WITH 1096 OG 30, THE FILING DATE ACCORDED EACH OFFICIAL FAX TRANSMISSION WILL BE DETERMINED BY THE FAX MACHINE DATE STAMP FOUND ON THE LAST PAGE OF THE TRANSMISSION, UNLESS THAT DATE IS A SATURDAY, SUNDAY, OR FEDERAL HOLIDAY WITHIN THE DISTRICT OF COLUMBIA, IN WHICH CASE THE OFFICIAL DATE OF RECEIPT WILL BE THE NEXT BUSINESS DAY.

THE DOCUMENT(S) ACCOMPANYING THIS FACSIMILE TRANSMISSION CONTAIN(S) INFORMATION FROM THE UNITED STATES PATENT AND TRADEMARK OFFICE WHICH IS CONFIDENTIAL AND/OR LEGALLY PRIVILEGED. THIS INFORMATION IS FOR THE USE OF THE INDIVIDUAL OR FIRM NAMED ON THIS SHEET. IF YOU ARE NOT THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT ANY DISCLOSURE, COPYING, DISTRIBUTION, OR THE TAKING OF ANY ACTION IN RELIANCE ON THE CONTENTS OF THIS INFORMATION IS STRICTLY PROHIBITED. THE DOCUMENTS SHOULD BE RETURNED TO THE PATENT AND TRADEMARK OFFICE IMMEDIATELY. IF THIS FACSIMILE IS RECEIVED IN ERROR, PLEASE NOTIFY THE ATTORNEY LISTED HEREON IMMEDIATELY.